

RESULTS FROM THE

2005

ANNUAL REPORT

SHOT - Organisation

- **SHOT was launched in 1996**
- **A UK-wide confidential, voluntary anonymised scheme which aims to collect data on adverse events of transfusion of blood and blood components, and to make recommendations to improve transfusion safety**
- **Based at Manchester Blood Centre**

SHOT - Organisation

Steering group

- Strategic direction and “ownership”
- Royal Colleges and professional bodies
- Affiliated to the Royal College of Pathologists

Standing Working Group

- Operational aspects

Funding

- Four UK Blood Services on pro-rata basis according to the number of red cells issued

SHOT - Aims

Through the participating Royal Colleges and professional bodies, SHOT findings can be used to:

- inform policy within transfusion services
- improve standards of hospital transfusion practice
- aid production of clinical guidelines for the use of blood components
- educate users on transfusion hazards and their prevention

Categories of adverse events covered in the 2005 report

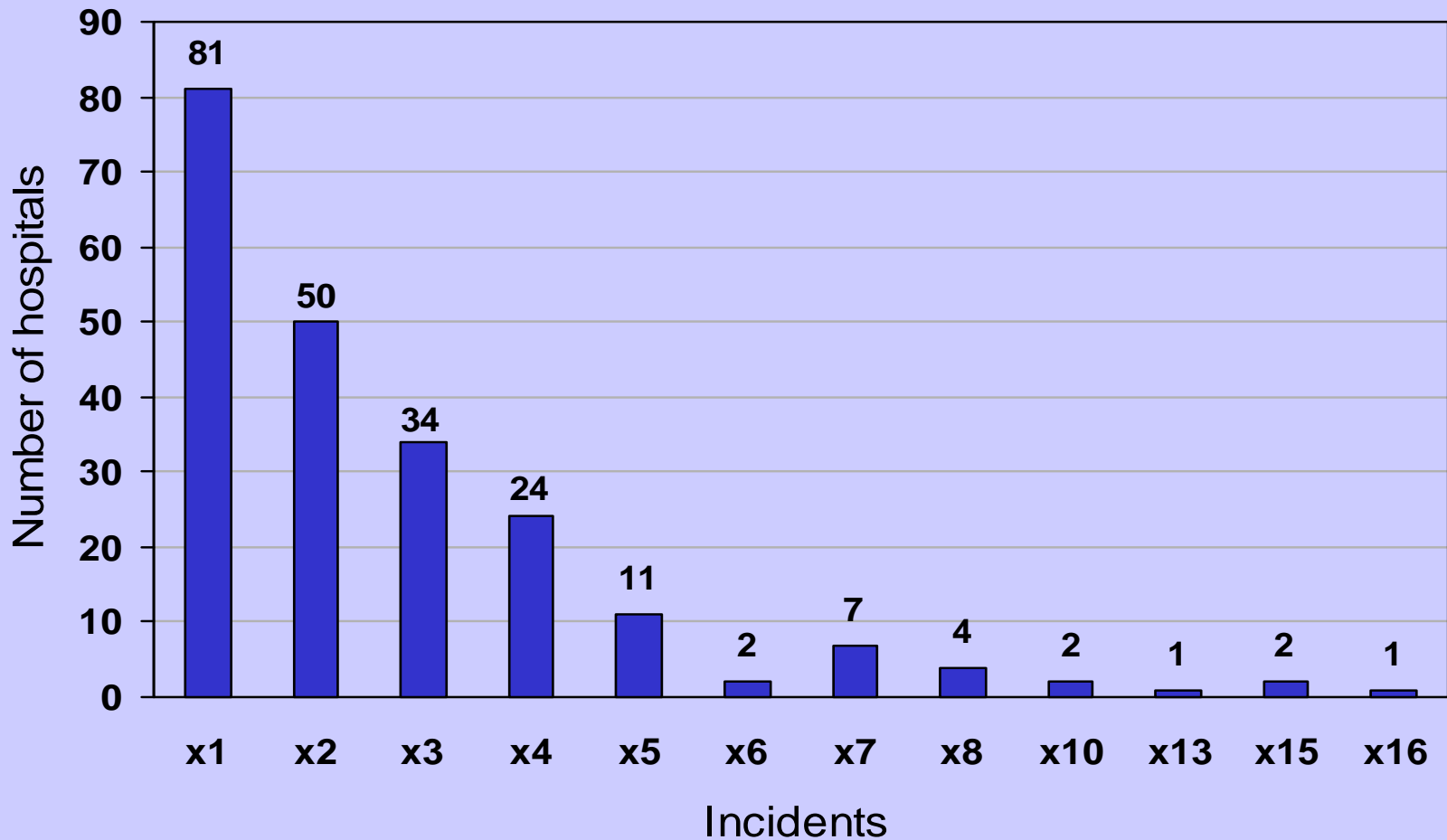
- **Incorrect blood/component transfused (IBCT)**
- **Acute transfusion reaction (ATR)**
- **Delayed transfusion reaction (DTR)**
- **Transfusion-associated graft-versus-host-disease (TA-GvHD)**
- **Transfusion-related acute lung injury (TRALI)**
- **Post-transfusion purpura (PTP)**
- **Transfusion transmitted infection, including bacterial contamination (TTI)**

Hospital participation - 2005

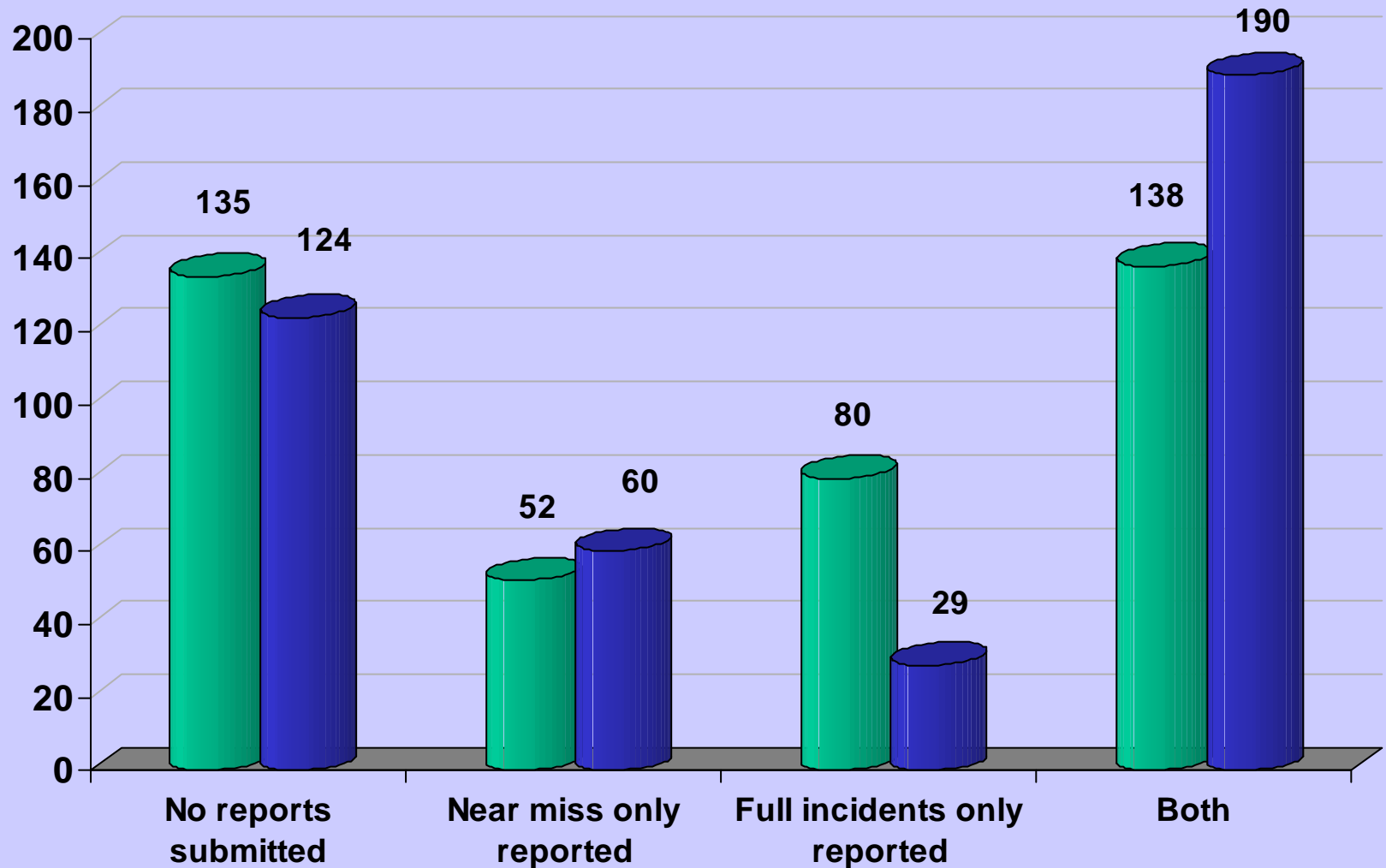
With the adoption of confidential ID numbers, SHOT is now able to provide every hospital with verification of participation.

- **54%** of eligible hospitals reported incidents in which a blood component was transfused.
- **69%** of eligible hospitals reported either at least one full incident or near miss.

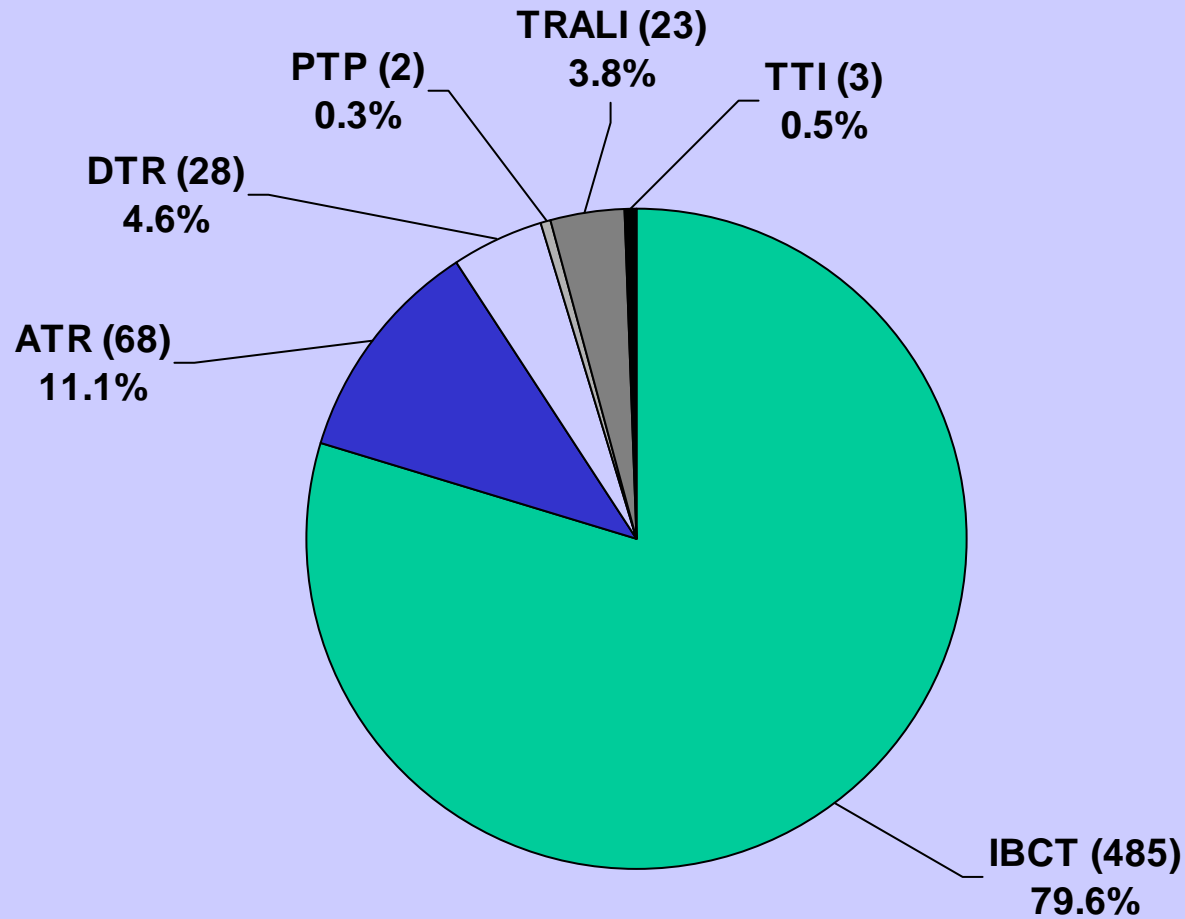
Numbers of incidents reported by individual hospitals 2005



Breakdown of hospital reporting 2004 & 2005



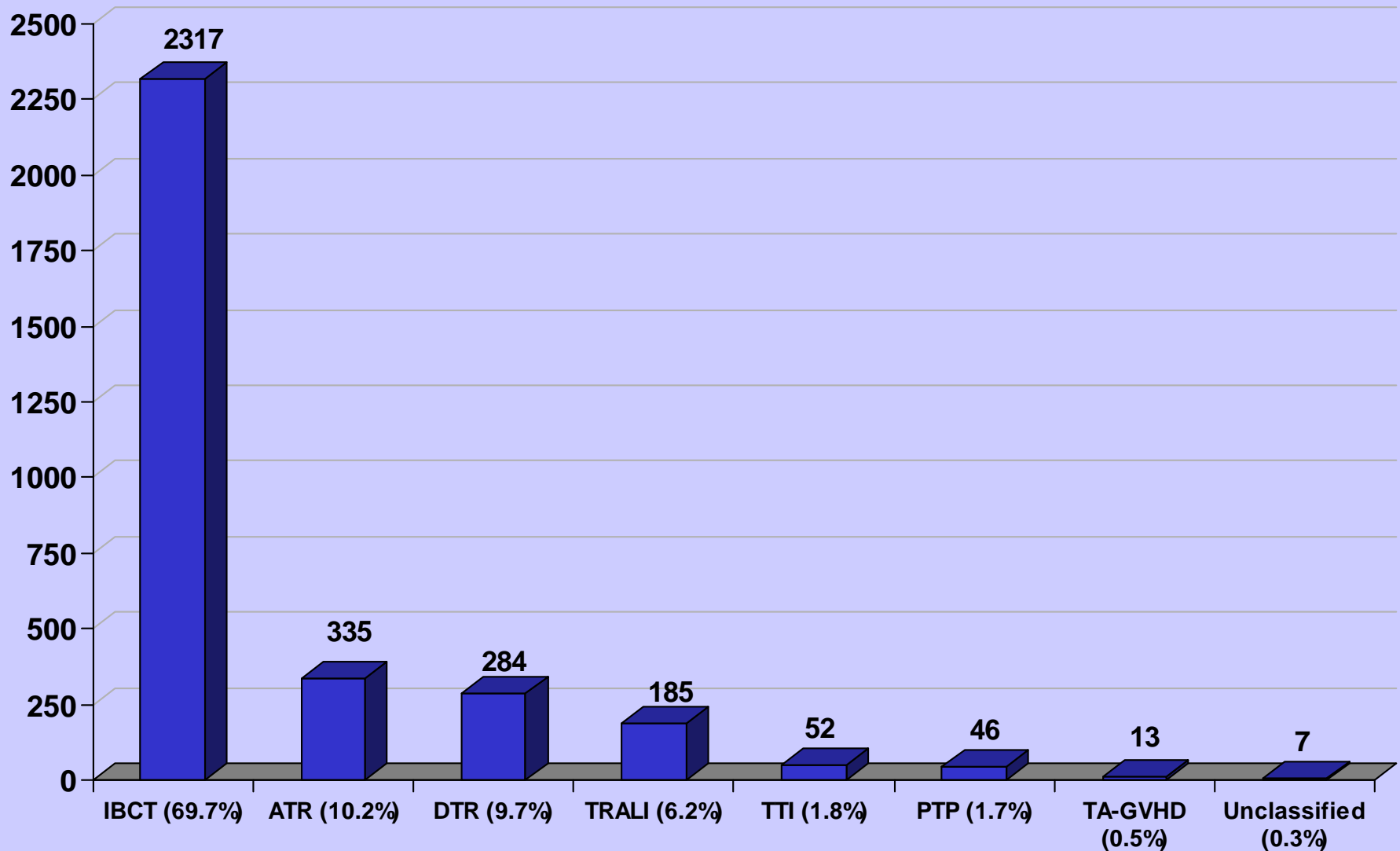
Summary of completed questionnaires (2005)



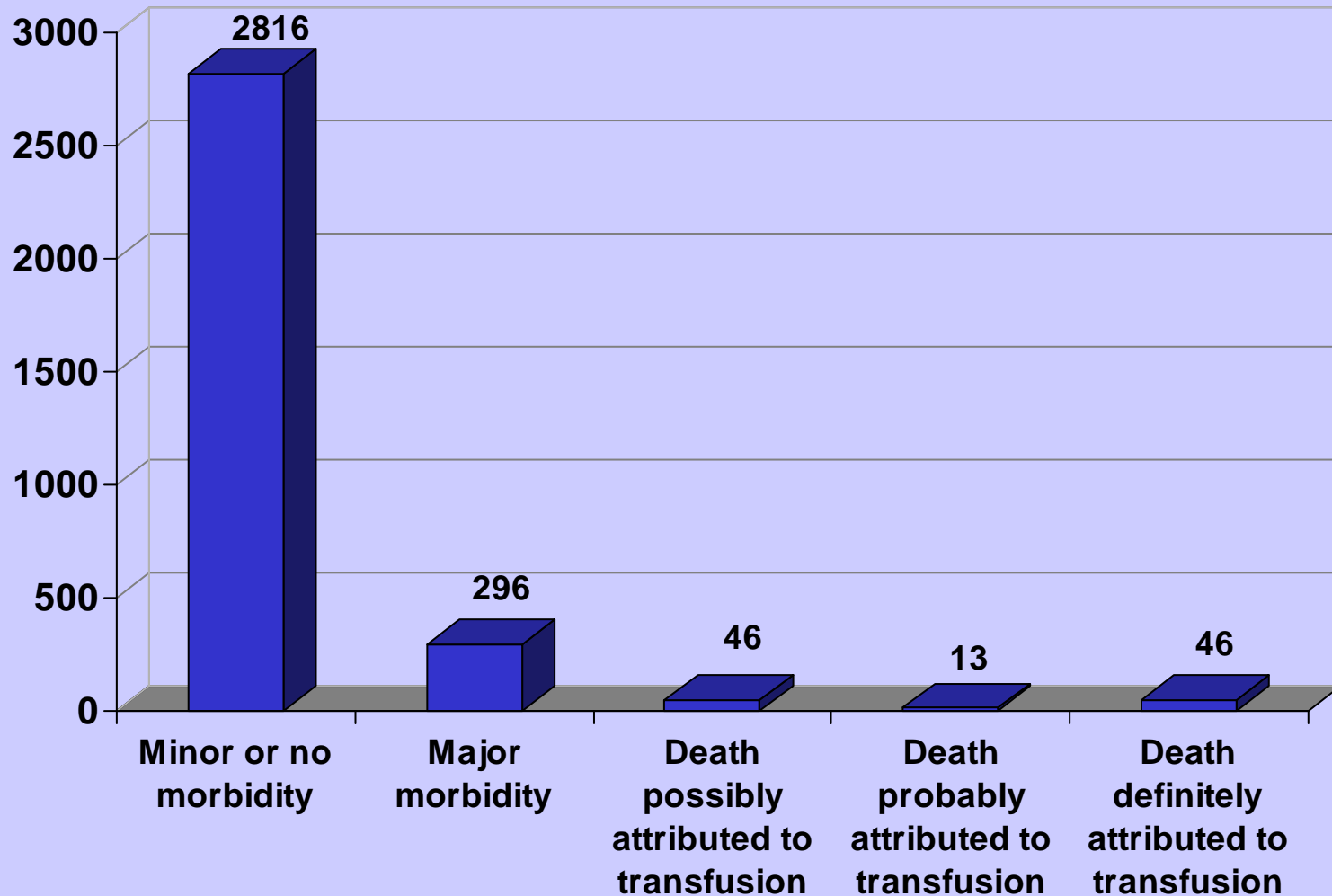
Cumulative data

1996-2005

Questionnaires analysed 1996 - 2005 (n=3239)



Cumulative mortality / morbidity table 1996-2005



Cumulative mortality / morbidity according to the type of hazard reported 1996 – 2005 (1)

	Total	IBCT	ATR	DTR	PTP	TA-GvHD	TRALI	TTI
Death definitely attributed to transfusion	46	7	2	6	1	13	8	9
Death probably attributed to transfusion	13	3	4	1	0	0	5	0
Death possibly attributed to transfusion	46	12	7	1	1	0	25	0
<i>Sub total 1</i>	<i>105</i>	<i>22</i>	<i>13</i>	<i>8</i>	<i>2</i>	<i>13</i>	<i>38</i>	<i>9</i>

Cumulative mortality / morbidity according to the type of hazard reported 1996 – 2005 (2)

	Total	IBCT	ATR	DTR	PTP	TA-GvHD	TRALI	TTI
Major morbidity	296	94	13	29	13	0	110	37
Minor or no morbidity	2816	2190	306	246	31	0	37	6
<i>Sub total 2</i>	<i>3112</i>	<i>2284</i>	<i>319</i>	<i>275</i>	<i>44</i>	<i>0</i>	<i>147</i>	<i>43</i>
TOTAL	3232	2317	335	284	13	13	185	52

Major morbidity was defined as the presence of one or more of the following;

- Intensive care admission and / or ventilation
- Dialysis and / or renal impairment
- Major haemorrhage from transfusion-induced coagulopathy
- Intravascular haemolysis
- Potential RhD sensitisation in a female of child-bearing potential

Incorrect blood component transfused (IBCT)

All reported episodes where a patient was transfused with a blood component or plasma product which did not meet the appropriate requirements or which was intended for another patient

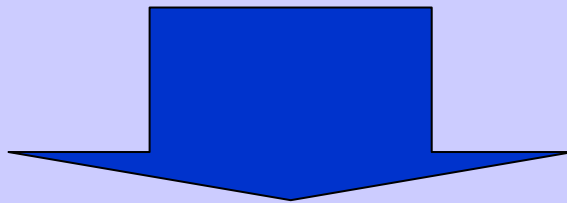
IBCT Cases reported 2005

524 completed questionnaires received

Of these;

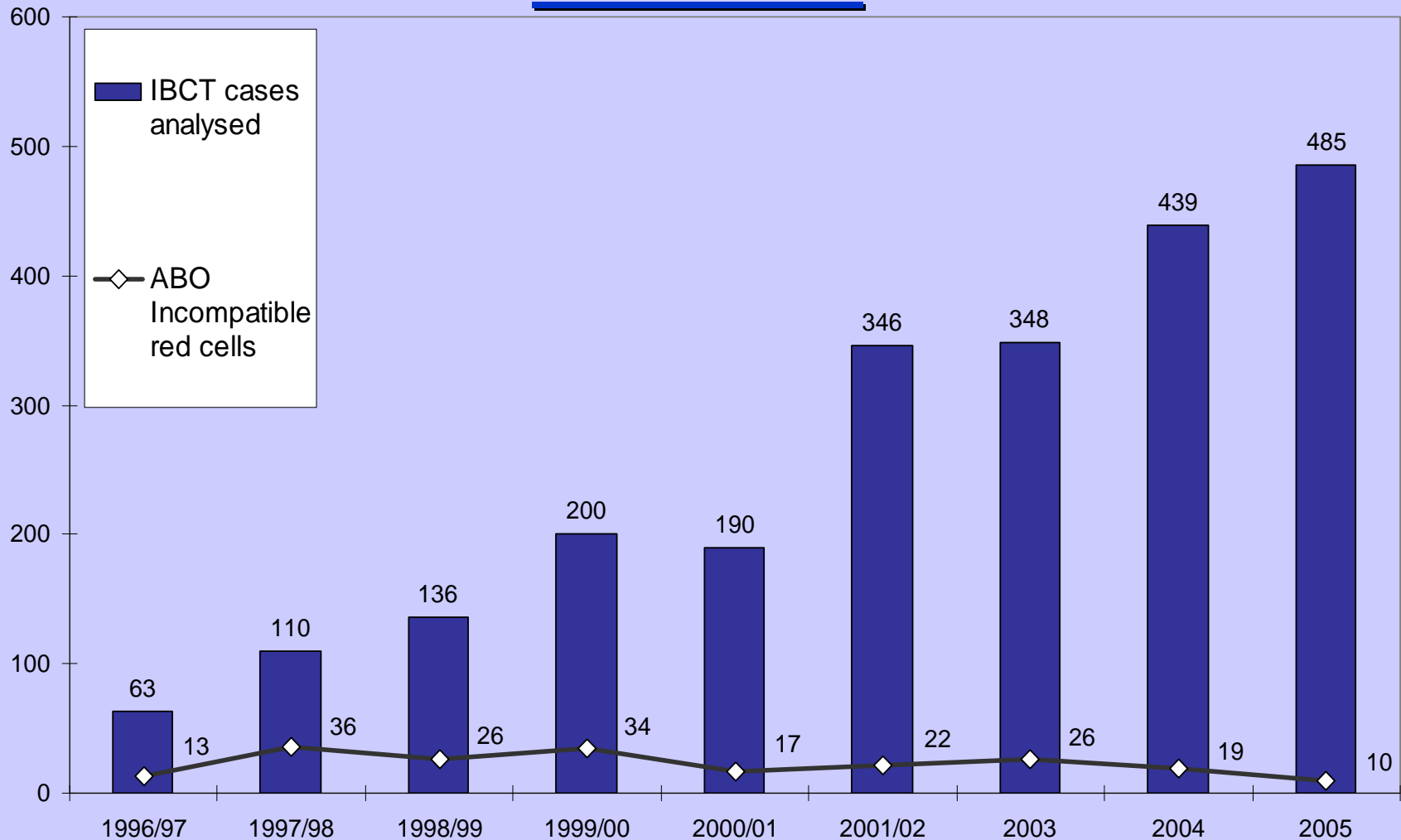
39 were withdrawn by the analyst

(**13** 'right blood to right patient' incidents, **26** did not meet IBCT criteria)



485 valid IBCT cases

ABO incompatible red cell transfusions 1996 - 2005



Mortality & morbidity - IBCT 2005

- **1** patient died following ABO incompatible red cell transfusion (imputability 3)
- **1** patient died, possibly related to overtransfusion (imputability 1)
- **1** patient suffered major morbidity due to overtransfusion (imputability 2)
- **1** recipient of an ABO incompatible haemopoietic stem cell transplant received blood of the incorrect group and suffered a severe acute haemolytic reaction

Cumulative mortality / morbidity data for IBCT cases 1996 - 2005 (n=2317)

Category	No. cases
Death definitely attributed to transfusion (imputability 3)	7
Death probably attributed to transfusion (imputability 2)	3
Death possibly attributed to transfusion (imputability 1)	12
Major morbidity	94
Minor or no morbidity	2190
Unknown outcome	11
Total	2317

Analysis of IBCT Cases

Type of Event	Number (%)
'Wrong Blood' events where a patient received a blood component intended for a different patient or of an incorrect group	87 (18%)
Other pre-transfusion testing errors – including incorrect D groups, missed allo-antibodies and missed serological incompatibility	22 (4.5%)
Blood of the incorrect group given to recipients of ABO mismatched PBSC or one marrow transplant.	2 (0.5%)
Failure to provide blood of appropriate specification or that did not meet the patient's special requirements.	141 (29%)
Inappropriate or unnecessary transfusions.	67 (14%)
'Unsafe' transfusions where there were handling or storage errors.	79 (16%)
Events relating to administration of anti-D immunoglobulin	87 (18%)
Total	485

1. 'Wrong Blood' Events (n=87)

- **10** patients received ABO incompatible red cell transfusions, 2 of which were also D incompatible.
- **9** patients received ABO incompatible FFP or cryoprecipitate (Group O components given to patients of other groups).
- **2** patients received ABO incompatible platelets (Group O to patients of other groups in error)
- **8** D negative patients received D positive cellular components - none was female of childbearing age.
- **1** patient with anti-c received group O rr red cells.
- **57** patients received components that were fortuitously compatible.

'Wrong Blood' Events - Site of Primary Error

Site of Primary Error	No. Cases (%)
CLINICAL (patient sampling)	4 (4.5%)
<i>Also laboratory error</i>	1
CLINICAL (wrong blood delivered to clinical area)	23 (26.4%)
<i>Also failure of bedside check</i>	23
CLINICAL (blood administered to wrong patient)	23 (26.4%)
LABORATORY	37 (42.5%)
<i>Also failure of bedside check</i>	4
Total cases	87
Total errors	115

'Wrong Blood' Events - Learning Points (1)

- Basic training for biomedical scientists must reiterate careful sample identification at the point of test.
- Robust systems must be in place for recording results of both manual and automated tests if electronic interfaces are not in place.
- Competency based training for laboratory staff must include those working out of hours.
- A laboratory quality system, as required by the Blood Safety & Quality Regulations, must include internal incident reporting mechanisms and appropriate, documented, corrective actions.

'Wrong Blood' Events - Learning Points (2)

- A final patient identification check must always be carried out before transfusion using the identity band or formally risk assessed alternative attached to the patient.
- Safety systems must be supported by training and education of all staff involved in transfusion, to ensure that correct procedures are followed.
- Routine pre-transfusion testing should not be done outside of core hours unless there are adequate numbers of appropriately skilled staff.

'Wrong Blood' Events - Learning Points (3)

- Administration of blood should only take place at night when clinically essential.
- Procedures must be in place for collection of blood from refrigerators and must include the requirement to check against the patient's minimum identification dataset.

2. Other Pre-transfusion Testing Errors (n=22)

- 10 / 22 were errors involving the antibody screen.
- 1 error involved a missed anti-A1.
- 1 error where a repeat antibody panel was not done.
- 2 cases where antigen negative units were not selected.
- 1 case where electronic issue was used when an IAT crossmatch should have been performed.
- 1 case where a laboratory failed to look for a masked allo-antibody in a patient with a positive DAT.
- 5 cases where labs failed to request fresh samples for pre-transfusion testing from recently-transfused patients.
- 1 case where a BMS entered negative results for a crossmatch that had not been performed.

3. Blood of wrong group given to recipients of ABO mismatched haemopoietic stem cell transplants (n=2)

- In one case, the laboratory was not informed that the patient had received a transplant, and only suspected this when discrepant ABO grouping results started to develop.
- In the second case the laboratory staff selected blood of the wrong group, then compounded the error by incorrectly performing the crossmatch and failing to detect incompatibility. The patient suffered an acute haemolytic reaction.

4. Failure to provide Components of appropriate specification or that did not meet special requirements (n=141)

Special requirement	No. of cases
Irradiated components	89
CMV Negative components	6
Irradiated and CMV negative	16
Antigen negative red cells for patient with known antibody	20
Antigen negative and irradiated	1
HPA 1a/5b negative platelets for NAITP	2
Neonatal red cell transfusion, exchange transfusion	4
Viral inactivated non-UK FFP for a child	1
HLA matched platelets	1
Pre-deposited autologous red cells	1
Total	141

Failure to provide irradiated components (n=106)

Indication for irradiated components	No. of cases
Purine analogue therapy	44
Stem cell transplantation	29
Hodgkin's Disease	17
Di George syndrome	5
Other T-cell immunodeficiency	2
Severe aplastic anaemia / ALG	3
Neonate, previous <i>in utero</i> transfusion	1
Miscellaneous	5
Total	106

Site of primary error that led to failure to provide irradiated components

Site of primary error	No. cases (%)
LABORATORY	30 (28%)
<i>(also clinical error)</i>	27
CLINICAL	70 (60%)
<i>(also laboratory error)</i>	9
ADMINISTRATIVE or I.T. ERROR	3
<i>(also laboratory or clinical error)</i>	2
PHARMACY	1
<i>(also laboratory or clinical error)</i>	1
BLOOD SERVICE	2
<i>(also laboratory or clinical error)</i>	2
Total	106

Learning Points (1)

- Hospital and laboratory IT systems should use compatible patient ID parameters to ensure that correct historical transfusion records are accessed rapidly and efficiently. Laboratory IT systems should be updated with special requirements and data should be transferred electronically to new systems. Systems should, if possible be updated with new rules eg MeBlue non-UK FFP for patients <16.
- Several laboratory errors were caused by failure to notice the *Special Requirements* box on the transfusion request form. The format of transfusion request forms should be reviewed to ensure this section is appropriately prominent. Electronic requesting systems should ensure completion of this section is mandatory. Laboratories should also insist on appropriate clinical details on request forms.

Learning Points (2)

- Clinicians have a responsibility to be aware of the special transfusion needs of their patients and to ensure that local systems for notifying the laboratory are followed. Hospitals should consider implementing a system of informing the laboratory as soon as transfusion for irradiated components is identified. In the case of purine analogue therapy, routine notification of the transfusion laboratory by the hospital pharmacy is an effective safety measure, although data should be transferred at frequent intervals to prevent patients receiving non-irradiated products in the 'window period'. Where patients have several volumes of hospital notes, each should be 'flagged' with the special requirements.

Learning Points (3)

- Blood request forms must be accurately completed and transfusion prescriptions must indicate special requirements.
- The final bedside check is the last barrier to mistransfusion and appears to fail in 20 - 40% of cases - research into ways of improving its effectiveness and evaluation of new technologies to improve the process is essential.
- Communication both between clinicians in specialist treatment centres and local hospitals, and between clinical teams within hospitals, must be improved. Data on special transfusion requirements should be communicated between transfusion laboratories in hospitals that routinely 'share' patients.

Learning Points (4)

- Greater emphasis should be placed on involving patients in ensuring their special transfusion requirements are met. Simply issuing 'Irradiated Component' cards to patients appears to have been of limited benefit. The introduction of a patient held booklet (analogous to the commonly used anticoagulant booklet), together with targeted education, should be considered for patients following stem cell transplantation and purine analogue therapy and would be a suitable area for clinical research and pilot studies.

5. Inappropriate or unnecessary transfusions (n=67)

Primary error	Number
Unsuitable sample for FBC eg from 'drip arm' or from wrong patient (CLINICAL)	27
<i>Also laboratory error</i>	6
<i>Also clinical (request) error</i>	5
Analytical error (HAEMATOLOGY LABORATORY)	10
<i>Also clinical (request) error</i>	2
Near-patient testing error (CLINICAL)	5
FBC misinterpreted or wrongly transcribed resulting in request error (CLINICAL)	5
Wrong component/product selected (TRANSFUSION LABORATORY)	4
Wrong component collected from hospital transfusion laboratory (CLINICAL)	9
<i>Also failure of pre-transfusion check against prescription</i>	15
Overtransfusion due to clinical misjudgement (CLINICAL)	7
Total cases	67
Total errors	95

Learning Points

- All staff undertaking phlebotomy must understand the importance of correct patient identification and correct sampling technique, and must be assessed as competent.
- Blood should only be prescribed by a doctor who has undergone training in blood transfusion and been assessed as competent.
- Diagnostic laboratories must carry out checks to identify large changes in parameters ('delta checks') and should communicate discrepancies to other laboratories.
- Near patient testing must be subject to the same standards of validation and quality assurance as the diagnostic laboratory.

6. 'Unsafe' transfusions (n=79)

Type of error	Number
Blood out of temperature control	43
Blood component given was past its expiry or suitability date	24
Blood components transfused over an excessive time period	9
Other	3
Total cases	79

Learning Points (1)

- The need for every satellite refrigerator should be carefully risk assessed and reviewed regularly. Clear protocols establishing the responsibilities of the laboratory and nursing staff must be implemented.
- Transfusion laboratory stock control procedures should ensure that expired units are cleared from issue locations.
- Nurses giving blood must be familiar with current guidelines on the handling of blood components.

Learning Points (2)

- Competency training for ward staff must reiterate the requirement for red cells to ONLY be stored in monitored blood refrigerators and must highlight the differences between a blood refrigerator and a normal ward refrigerator.
- Pre-transfusion checking procedures must include checking of the expiry date of the component and noting any end-date for suitability provided by the laboratory.

7. Adverse events relating to anti-D immunoglobulin (Ig) (n=87)

Type of event	Number
Omission or late administration of anti-D Ig	27
Anti-D Ig given to D positive patient	23
Anti-D Ig given to patient with immune anti-D	7
Anti-D Ig given to patient with weak D antigen	6
Anti-D Ig given to mother of D negative infant	7
Anti-D Ig given to wrong patient	6
Expired anti-D Ig given	9
Other	2
Total cases	87
Total errors	93

Learning Points

- Training and competency assessment of BMSs in antenatal serology testing and the indications for issue of anti-D Ig must be comprehensive.
- There is an urgent need for education of primary care staff in the basic principles of antenatal serology and current relevant guidelines.

Summary of blood transfusion laboratory errors - all cases (where known)

	Total errors	Wrong sample	Transcription	Interpretation	Component selection errors	Labelling	Procedural errors	Incorrect protocol	Testing	Not known
Wrong Blood – ABO	22	9	10	2						1
Wrong Blood - Others	15	3	1		9	1				1
ABO mismatched transplant	1						1			
Special requirements not met	72				72					
Inappropriate transfusion	4				4					
Anti-D errors	23	1	3				13	1	5	
Unsafe transfusion	20						20			
Other pre-tx testing errors	22						15		7	
Total errors	179	13	14	2	85	1	49	1	12	2

'Right blood to right patient' - RBRP (n=67)

Elements which were wrong on blood packs, documentation, ID bands etc.	No of incidents
DOB alone or with other elements	22
Name alone or with other elements	16
Hospital or NHS number	11
Transposed labels on 2 units	7
Units unlabelled	3
Hospital transfusion lab records not signed on collection	3
Miscellaneous:	
2 labels on 1 unit	1
Address only	1
Platelets issues retrospectively	1
DOB missing completely	1
1 unit given without prescription	1

RBRP - the checking procedures that failed to identify the error(s)

Checking procedures	No. of incidents
Bedside checking	40
Clinical decision to proceed	5
Laboratory + collection + bedside checking	4
Laboratory	3
Sampling + bedside checking	2
Laboratory + bedside checking	2
Collection	1
Collection + bedside checking	1
Blood centre + laboratory + bedside checking	1

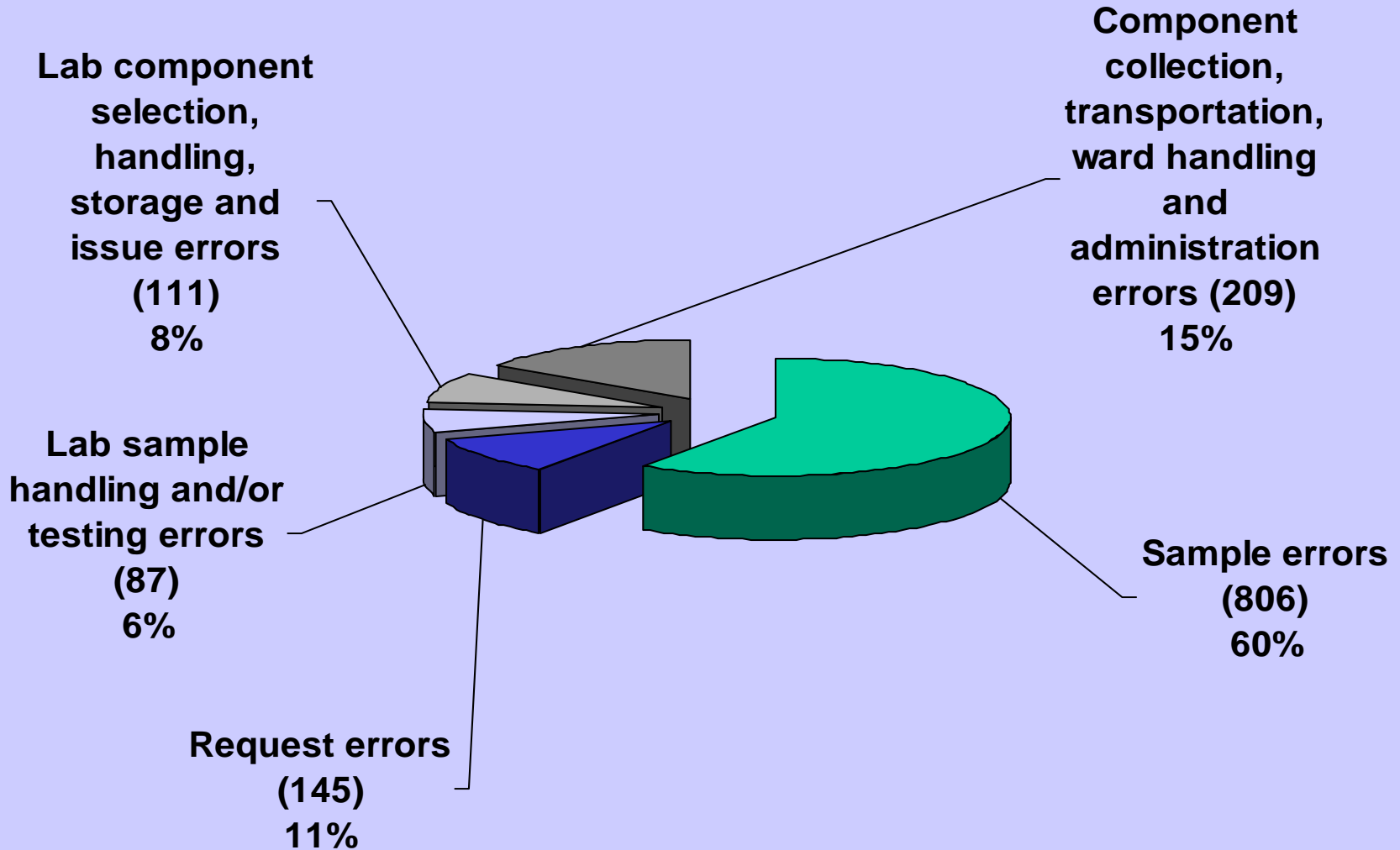
Learning Points

- Clinicians should be aware of the potential dangers of transfusing patients when the checking process has highlighted a discrepancy in available information. If the situation is not an emergency it must be standard policy not to transfuse and to begin the process again.
- Staff carrying out the bedside check must check all details in minute detail since a discrepancy in only one letter or digit is potentially dangerous.

Near Miss Events

Any error which, if undetected, could result in the determination of a wrong blood group, or issue, collection or administration of an incorrect, inappropriate or unsuitable component, but which was recognised before transfusion took place

Near Miss Events



Types of “Near miss” events

- Sample errors (806)
- Request errors (145)
- Laboratory sample handling &/or testing errors (87)
- Laboratory component selection, handling, storage & issue errors (111)
- Component collection, transportation, ward handling & administration errors (209)

Near miss Errors - Commentary

- Errors at the sampling stage comprise over 50% of near miss incidents reported.
- Medical staff were involved in 57% of these errors.
- 10% of errors occurred at the request stage, mainly detected by laboratory staff.
- Laboratory staff failed to provide for patients special requirements in 39% of the laboratory component selection, handling, storage and issue category.
- Components were inappropriately handled or stored in 62% of the cases in the component transportation, ward handling and administration errors category.

Recommendations (1)

- Training and education in blood sampling, including positive patient ID, should be included in the curriculum for all staff involved in venepuncture.
Action: CMOs, NBTC and counterparts, Undergraduate Deans of Schools of Nursing and Medicine.
- All staff involved in the pre-transfusion sampling, testing and issue of blood must be deemed competent having undergone appropriate training, which must be documented
Action: Trust CEOs through risk management structures.

Recommendations (2)

- Ward staff at all levels must be trained in appropriate storage of blood components once they have been collected from the transfusion laboratory.

Action: Ward managers, HTTs.

Acute transfusion reactions

Acute transfusion reactions are defined in this report as those occurring at any time up to 24 hours following a transfusion of blood or components, excluding cases of acute reactions due to incorrect component being transfused

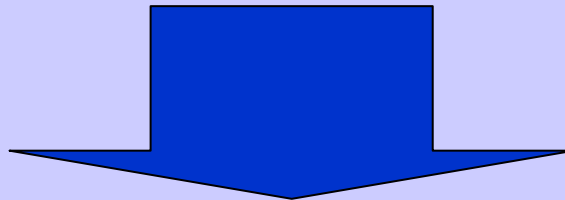
Cases reported

89 completed questionnaires submitted for analysis

Of these;

21 reports were withdrawn by the analyst

(**15** febrile non-haemolytic reactions, **5** where the symptoms were due to underlying pathology and one where no reaction occurred)



68 valid acute transfusion reactions

Outcomes and imputability

Outcome	Imputability level	Case No.	Component	Reaction type	Comment
Death	2	10	FFP	Anaphylactic/ anaphylactoid	Obstructive jaundice. Vit K not given
Major morbidity	2	6	Red cells	Anaphylactic/ anaphylactoid	Cardiac arrest, severely atopic recipient
	2	8	Red cells	Unclassifiable	Hypoxia requiring ventilation
	2	11	FFP	Anaphylactic/ anaphylactoid	Cardiac arrest
	2	12	FFP	Anaphylactic/ anaphylactoid	Myocardial infarct
	2	13	Platelets	Unclassifiable	Respiratory arrest
	2	14	Granulocytes (from family member)	Anaphylactic/ anaphylactoid	Ventricular tachycardia
	1	9	Red cells	ALI	Multiple factors

Components implicated & types of reaction (n=34)

Reaction type	Red cells	FFP	Platelets	Granulocytes	Totals
Haemolytic	5				5
Anaphylactic*	5	14	5	1	25
Allergic**	8	9	11		28
Hypotension		1	3		4
Unclassifiable	2		1		3
Febrile	3				3
Totals	23	24	20	1	68

* anaphylactic/anaphylactoid (hypotension with 1 or more of: rash, dyspnoea, angioedema)

** allergic (1 or more of: rash, dyspnoea or angioedema **without** hypotension)

Time interval between reaction & medical examination

Time before seen by a doctor	Red cells	FFP	Platelets
< 15 minutes	12	20	15
< 30 minutes	3	1	3
< 60 minutes	2		1
> 60 minutes	2		
Unknown	4	3	2
Total	23	24	21
Haematologist involved	19	10	15
Reporting mechanism			
Reported to HTC	20	16	16
Reported to hospital laboratory	23	24	20
Reported to blood centre	18	7	12

Recommendations (1)

- Pre-transfusion testing on patients who have recently been transfused and require further transfusion should be carried out in accordance with BCSH guidelines relating to the timing of pre-transfusion samples.

Action : Hospital transfusion laboratories

Recommendations (2)

- BCSH guidelines on the management of anticoagulation in the peri-operative period and on the management of excessive anticoagulation should be followed. Excessive anticoagulation with minor haemorrhage should be treated by stopping the drug and if necessary with intravenous vitamin K.
- BCSH guidelines for the use of FFP should be followed. Its use for the correction of abnormal coagulation results in the absence of bleeding is not justified

Action: Consultant haematologists with responsibility for transfusion should ensure that BCSH guidelines are incorporated into local protocols

Recommendations (3)

- All serious transfusion reactions must be investigated. Bacterial cultures must be taken in a febrile reaction, when the rise in temperature exceeds 1.5°C or the reaction is otherwise severe to merit discontinuing transfusion. An update of BCSH guidelines is in progress.

Action: Consultant haematologists with responsibility for transfusion should implement current best practice.

- Blood should not be transfused out of core hours unless clinically essential .

Action: Hospital CEOs, consultant haematologists with responsibility for transfusion together with HTC and HTTs

Recommendations (4)

- Against the background of a trend towards provision of care closer to the patient, there is a need for a standard of practice to be developed for transfusion in the community setting, including provision for appropriate management and reporting of adverse reactions and events.

Action: UK National Blood transfusion Committees to facilitate and co-ordinate.

Delayed transfusion reactions

Delayed transfusion reactions are defined in this report as those occurring more than 24 hours following a transfusion of blood or blood components. In practice, these are usually delayed haemolytic reactions due to the development of red cell alloantibodies.

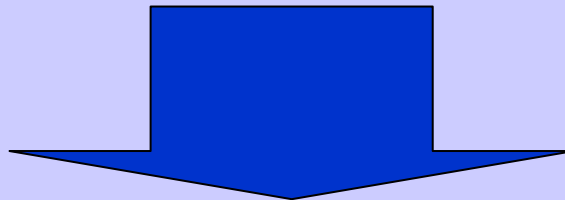
Simple serological reactions (antibody development without a positive DAT or evidence of haemolysis) are excluded.

Cases reported

29 completed questionnaires submitted for analysis

Of these;

1 case was reclassified as an Acute Transfusion Reaction

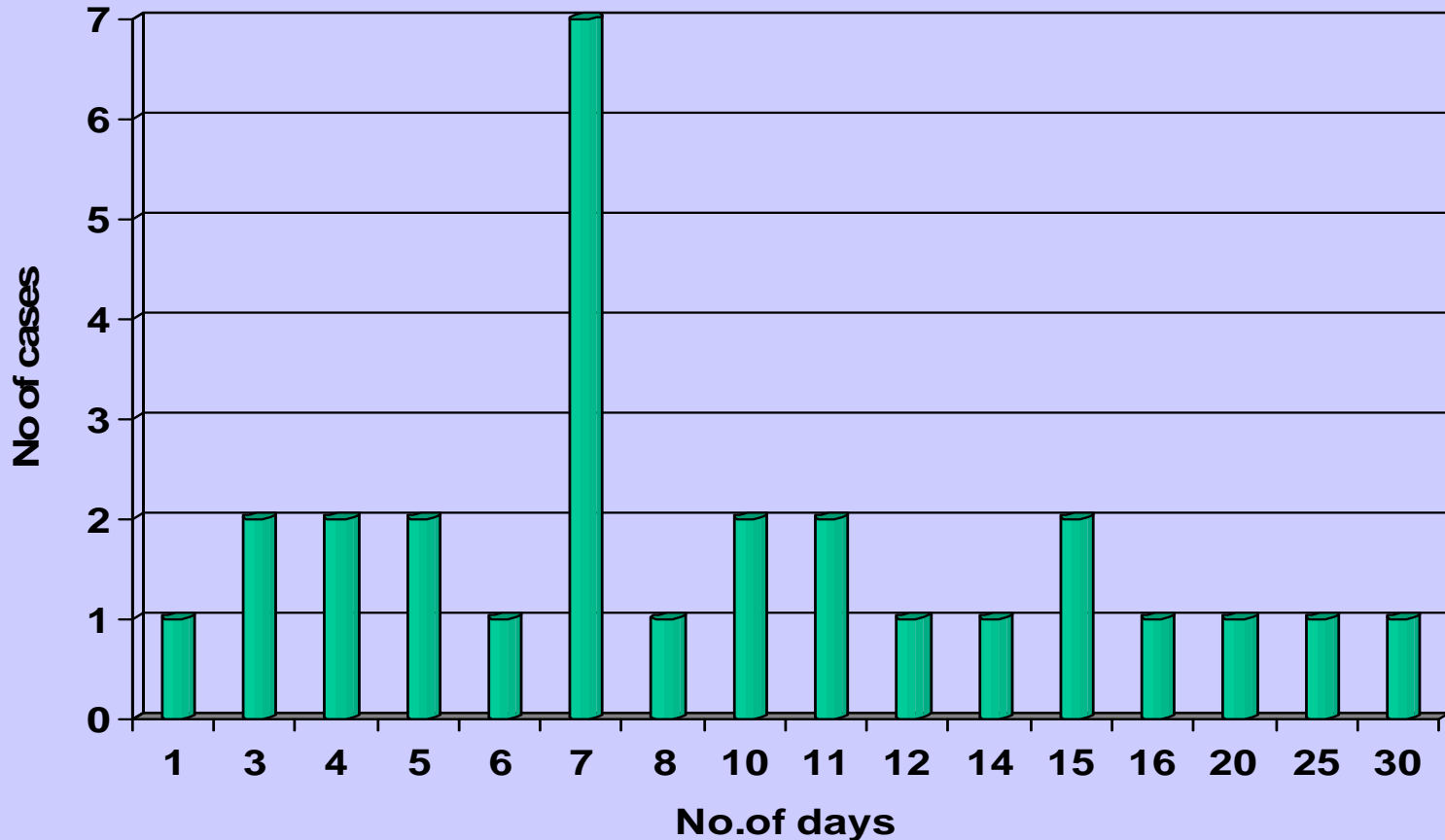


28 valid delayed transfusion reactions

Outcomes and imputability

- **1** patients required ICU admission and subsequently died - thought to be unrelated to transfusion - imputability 0
- **6** patients were asymptomatic with a positive DAT and antibody development only.
- **22** patients had evidence of increased red cell destruction without renal impairment.
 - In 7 cases, the only sign was a fall in haemoglobin, with or without a positive DAT and spherocytes
 - In 15 cases there was a fall in haemoglobin and a raised plasma bilirubin, although clinically detectable jaundice was only reported in 5 cases. One of these patients died, with no evidence that the death was related to transfusion and no detectable alloantibody.

Time relationship to transfusion



The interval in days between the implicated transfusion & signs or symptoms of a DHTR are shown. The intervals given are necessarily those when the signs or symptoms were first noted; in asymptomatic cases this relates to the number of days that elapsed before a repeat sample happened to be tested

New specificities by blood group system

Antibody specificity by blood group system	Number of cases	Sole <i>new</i> antibody
Kidd		
JK ^a	8	4
JK ^b	3	1
Rh		
C	1	1
E	7	0
c	3	0
Kell		
K	1	0
Duffy		
Fy ^a	6	4
MNSs		
S	3	3
M (37deg.C)	2	2
Other		
Lu ^a	1	0
Unspecified low incidence	1	0
Non-specific	1	1

Recommendations (1)

- All cases of suspected AHTR and DHTR should be appropriately investigated, and ideally referred to a reference laboratory. Referring hospitals should make it clear to reference laboratories that they are investigating a DHTR to ensure that timely, appropriate tests are undertaken. Clinical details should be completed on the request forms, and the donation numbers of the units transfused should be included, so that their phenotype may be determined. Reference laboratories should ensure that investigation of DHTRs includes testing an eluate made from the patient's red cells when the DAT is positive.

Action: Hospital blood transfusion laboratories and reference laboratories

Recommendations (2)

- Inconclusive antibody screens should be investigated prior to transfusion and results confirmed with a reference laboratory if necessary.
- Investigation of a suspected DHTR should include re-testing of the pre-transfusion sample (where still available) by different or more sensitive techniques. Consideration should also be given to requesting clotted samples for investigation of suspected DHTRs and using polyspecific antihuman globulin (AHG). These actions may involve referral to a reference centre.

Action: Hospital blood transfusion laboratories

Recommendations (3)

- Hospitals and reference laboratories should be encouraged to publish case reports of DHTRs, after appropriate investigations have been undertaken, and where the implicated antibody is not recognised as a common cause of such reactions.

Action: Hospital blood transfusion laboratories and reference laboratories.

Recommendations (4)

- In line with recommendations made in the BCSH guidelines, consideration should be given to issuing antibody cards or similar information to all patients with clinically significant red cell antibodies. These should be accompanied by patient information leaflets, explaining the significance of the antibody and impressing that the card should be shown in the event of a hospital admission or being crossmatched for surgery. Laboratories should be informed when patients carrying antibody cards are admitted.

Action: The CMO's NBTC and its counterparts in Scotland, Wales, and Northern Ireland

Recommendations (5)

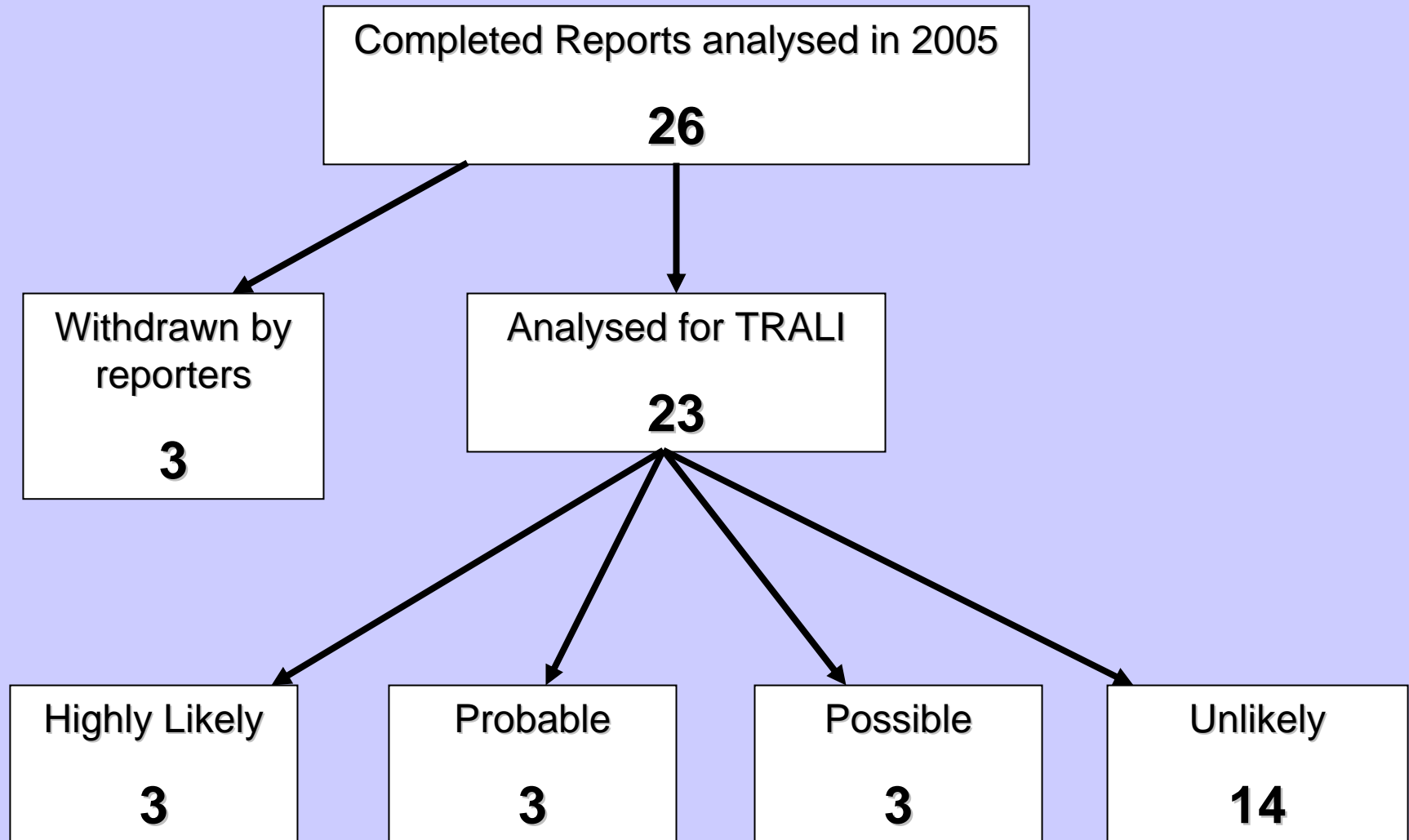
- There is a need for a review, co-ordinated by a professional national body, of how long specimens should be kept post-transfusion. The review needs to consider the relative risks and benefits of storing specimens beyond the time that they are suitable for use in further crossmatching tests.

Action: BBTS and BCSH

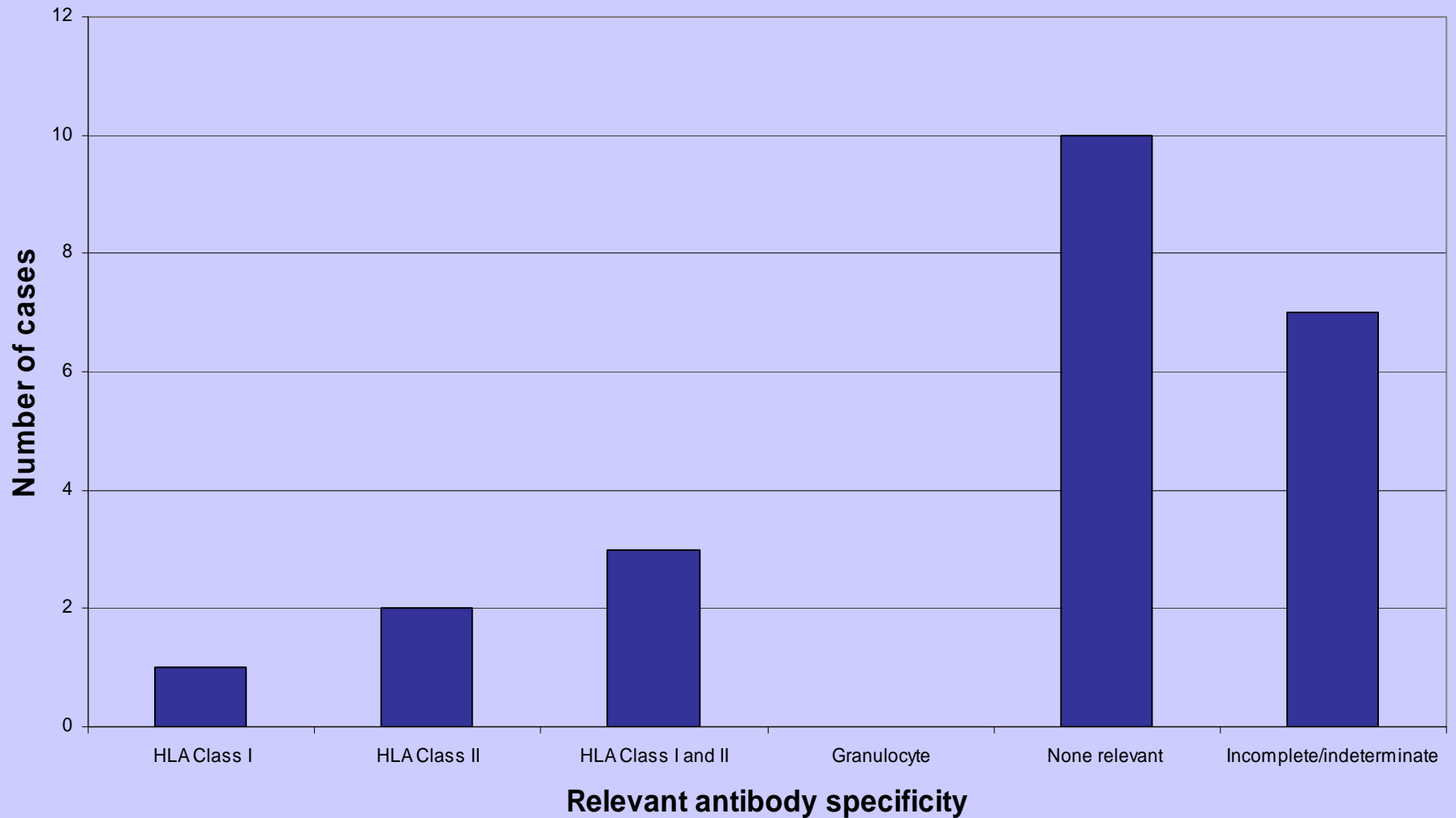
Transfusion Related Acute Lung Injury (TRALI)

Transfusion Related Acute Lung Injury was defined in this report as acute dyspnoea with hypoxia & bilateral pulmonary infiltrates occurring during or in the 24 hours after transfusion, with no other apparent cause.

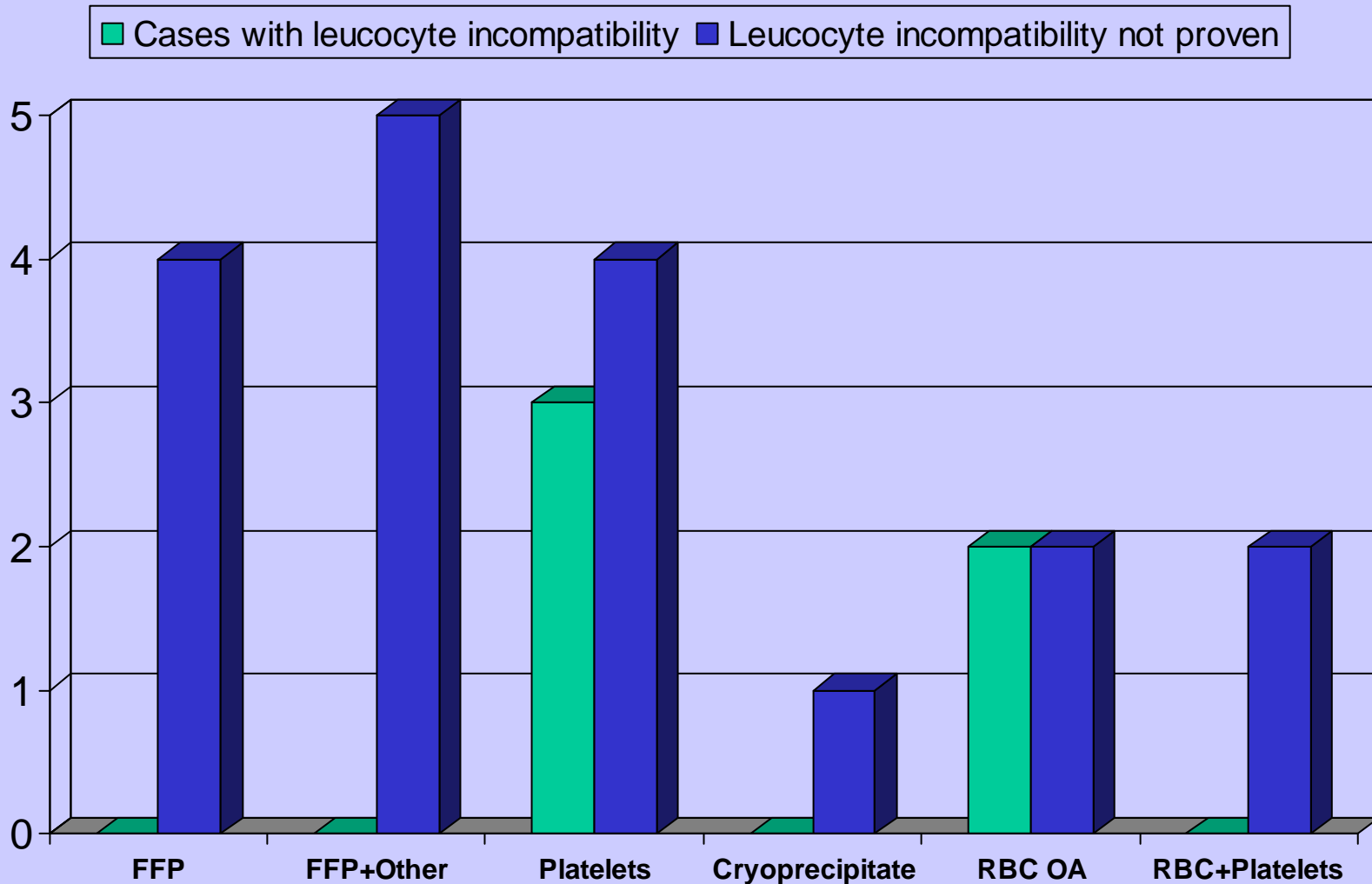
Summary of cases reported



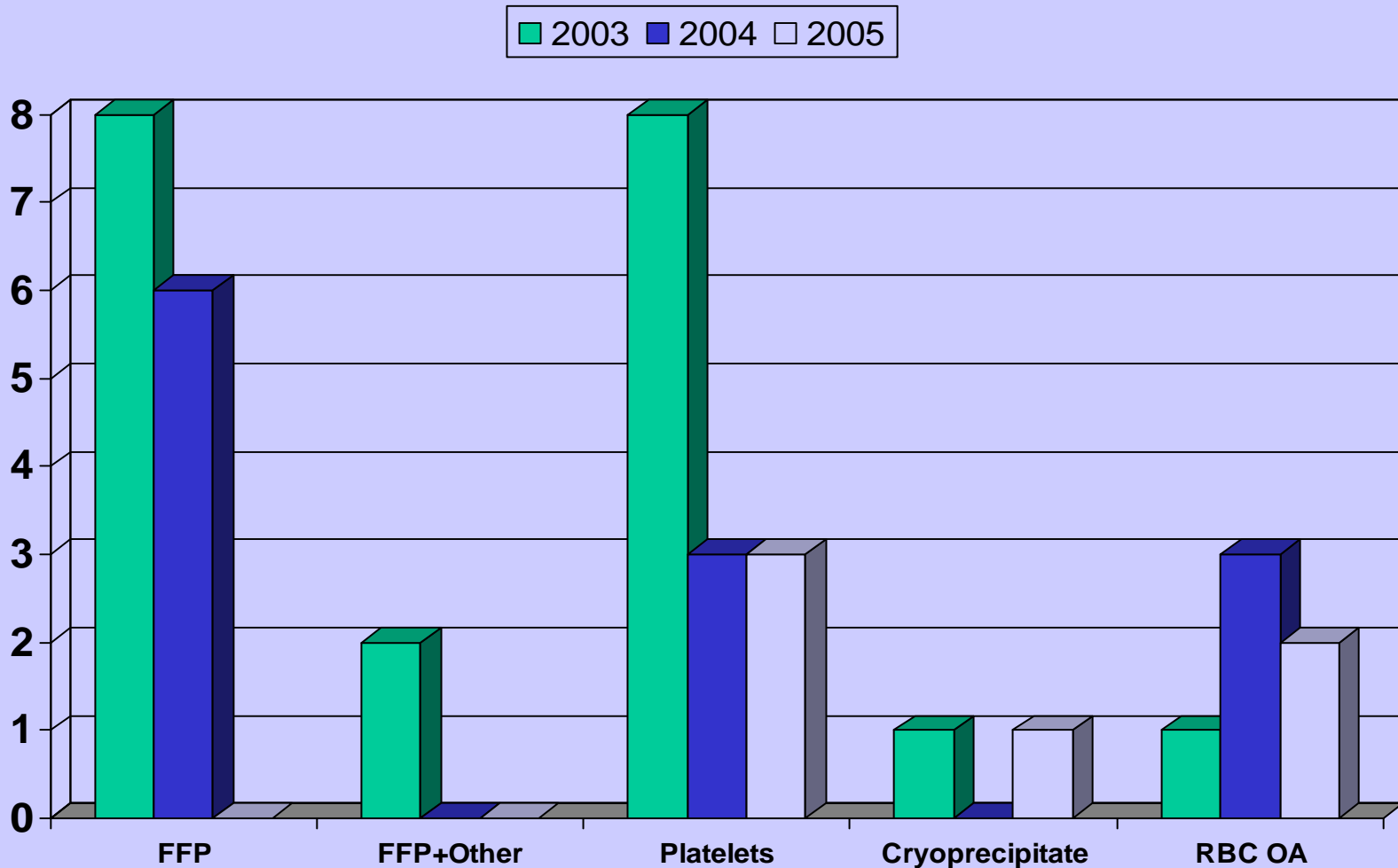
Implicated donor antibodies in TRALI



Analysis of components implicated in TRALI



Cases of TRALI with relevant donor antibody analysed by implicated component and by year 2003-2005



Recommendations (1)

- Hospital staff should continue to be aware of TRALI and report possible cases to the local Blood Centre to facilitate investigation. Detailed clinical information is needed to allow accurate assessment of these cases. Blood samples (clotted and EDTA) from affected patients should be sent for laboratory investigation early. Continued education of all relevant staff about this condition is encouraged.

Action: HTTs

Recommendations (2)

- Cases should be evaluated early by the consultant(s) involved and there should be early liaison with the local Blood Centre. There should be a team approach including the haematologist and chest physician and/or ICU consultant.

Action: Clinical users of blood and consultant haematologists with responsibility for transfusion.

- Serological investigation of suspected TRALI cases must include tests for antibodies to HLA Class I, HLA Class II and granulocyte-specific antigens.

Action: Reference laboratories

Recommendations (3)

- UK Blood Services must continue to keep female contributions to FFP and plasma for platelet pools to an absolute minimum.

Action: UK Blood Services

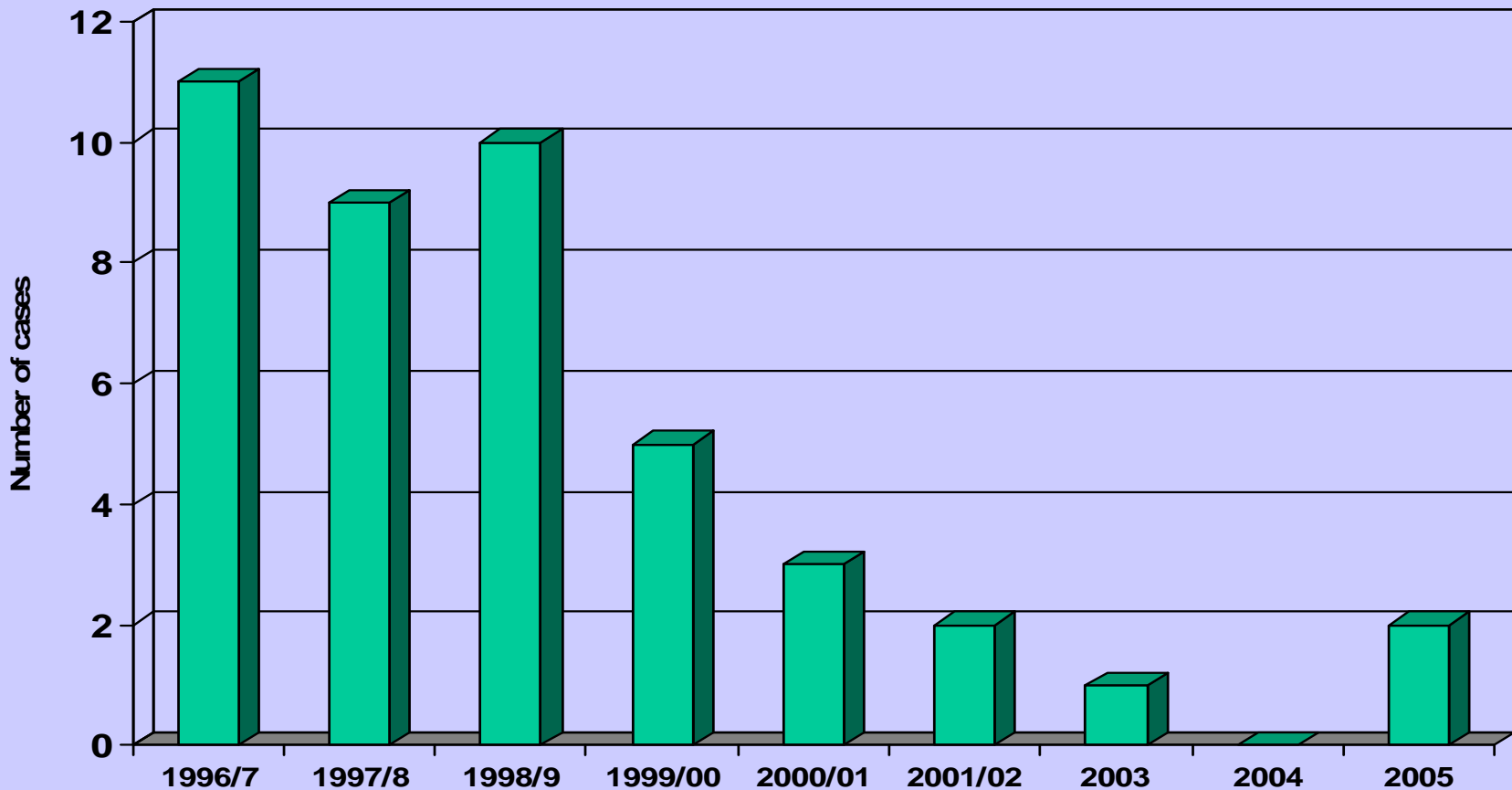
- Further TRALI risk reduction might be achieved by preferential recruitment of male apheresis platelet donors, screening female platelet donors for leucocyte antibodies or by replacing part of the supernatant plasma with additive solution.

Action: UK Blood Services

Post-Transfusion Purpura

Post-transfusion purpura was defined as thrombocytopenia arising 5 - 12 days following transfusion of red cells associated with the presence in the patient of antibodies directed against the HPA (Human Platelet Antigen) systems

Number of cases of confirmed PTP reported to SHOT each year



Recommendations

- Clinicians need to maintain awareness of this rare but treatable complication of transfusion.
- When PTP is suspected there should be referral to a platelet reference laboratory for relevant investigation.

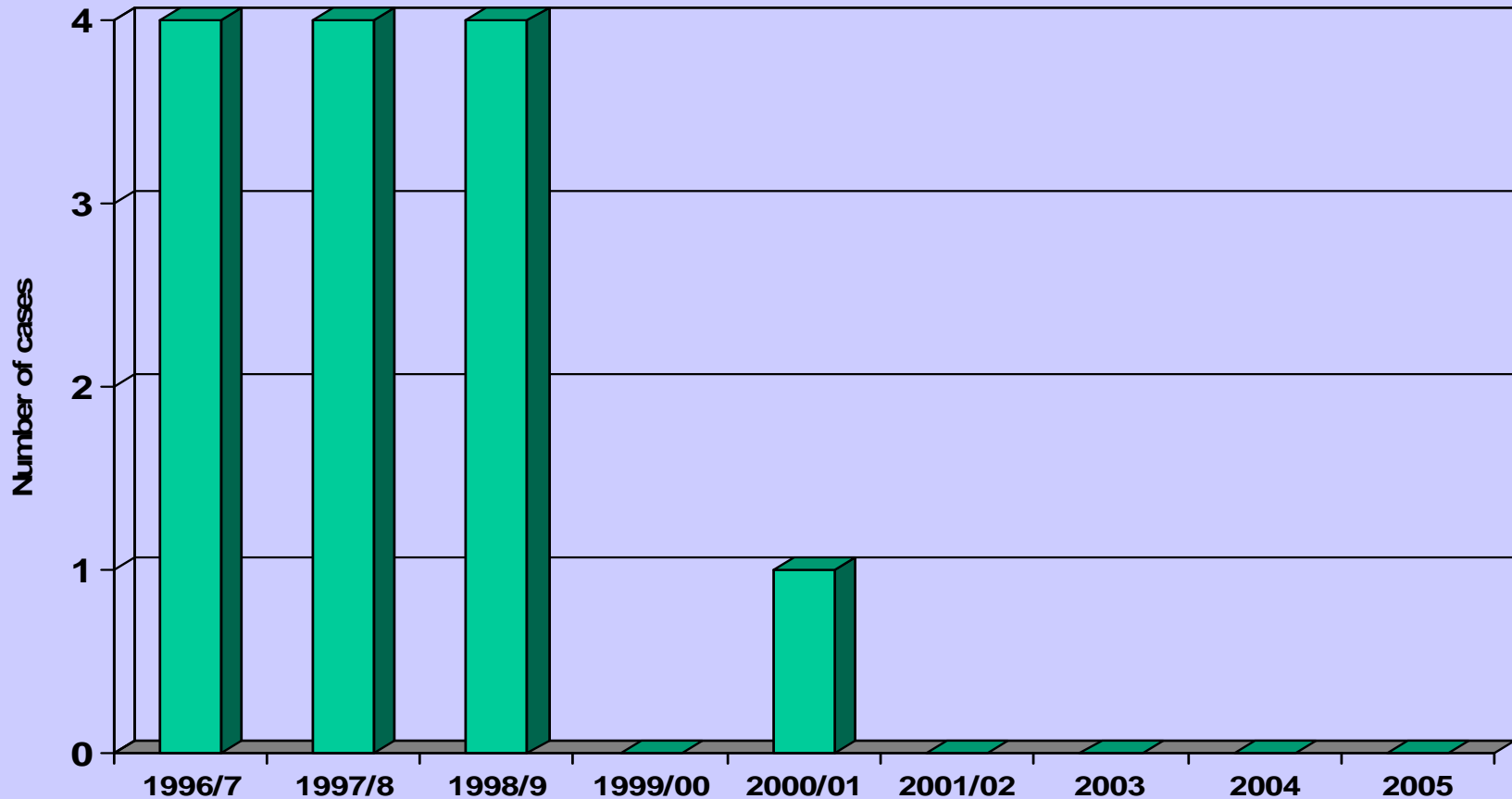
Action: Clinical users of blood and consultant haematologists with responsibility for transfusion.

Transfusion Associated-Graft versus Host Disease

Transfusion associated-graft versus host disease is a generally fatal immunological complication of transfusion practice, involving the engraftment and clonal expansion of viable donor lymphocytes, contained in blood components in a susceptible host.

TA-GvHD is characterised by fever, rash, liver dysfunction, diarrhoea, pancytopenia and bone marrow hypoplasia occurring less than 30 days following transfusion. The diagnosis is usually supported by skin/bone marrow biopsy appearance and/or the identification of donor-derived cells, chromosomes or DNA in the patient's blood and/or affected tissues.

Number of cases of TA-GvHD reported to SHOT each year



Recommendations (1)

- Gamma irradiation of blood components for those at risk of TA-GvHD remains essential. BCSH Blood Transfusion Task Force Guidelines define groups requiring this prophylaxis.

Action: Consultant haematologists with responsibility for transfusion should ensure that BCSH guidelines are incorporated into local protocols

Recommendations (2)

- Awareness of the potential for this condition must be maintained by all involved in the transfusion process.
- Good communication is required in all cases, but particularly when patient care is shared between different hospitals. Hospitals must have clear protocols to ensure accurate information relating to this risk is communicated in a timely manner. Provision of the BCSH/NBS patient card are also recommended.

Action: UK National and Regional Blood Transfusion Committees to facilitate and co-ordinate, Hospital CEOs to implement.

Recommendations (3)

- New chemo or immuno-therapeutic regimens must be evaluated for their potential to predispose individuals to TA-GvHD.

Regular update of guidelines is required to include up to date recommendations relating to drugs and protocols with potent immunosuppressive effects.

Action: BCSH

Transfusion transmitted infections

Reports are classified as TTI if, following investigation:

- The recipient had evidence of infection post-transfusion, and there was no evidence of infection prior to transfusion and no evidence of an alternative source of infection

And, either

- At least one component received by the infected recipient was donated by a donor who had evidence of the same transmissible infection,

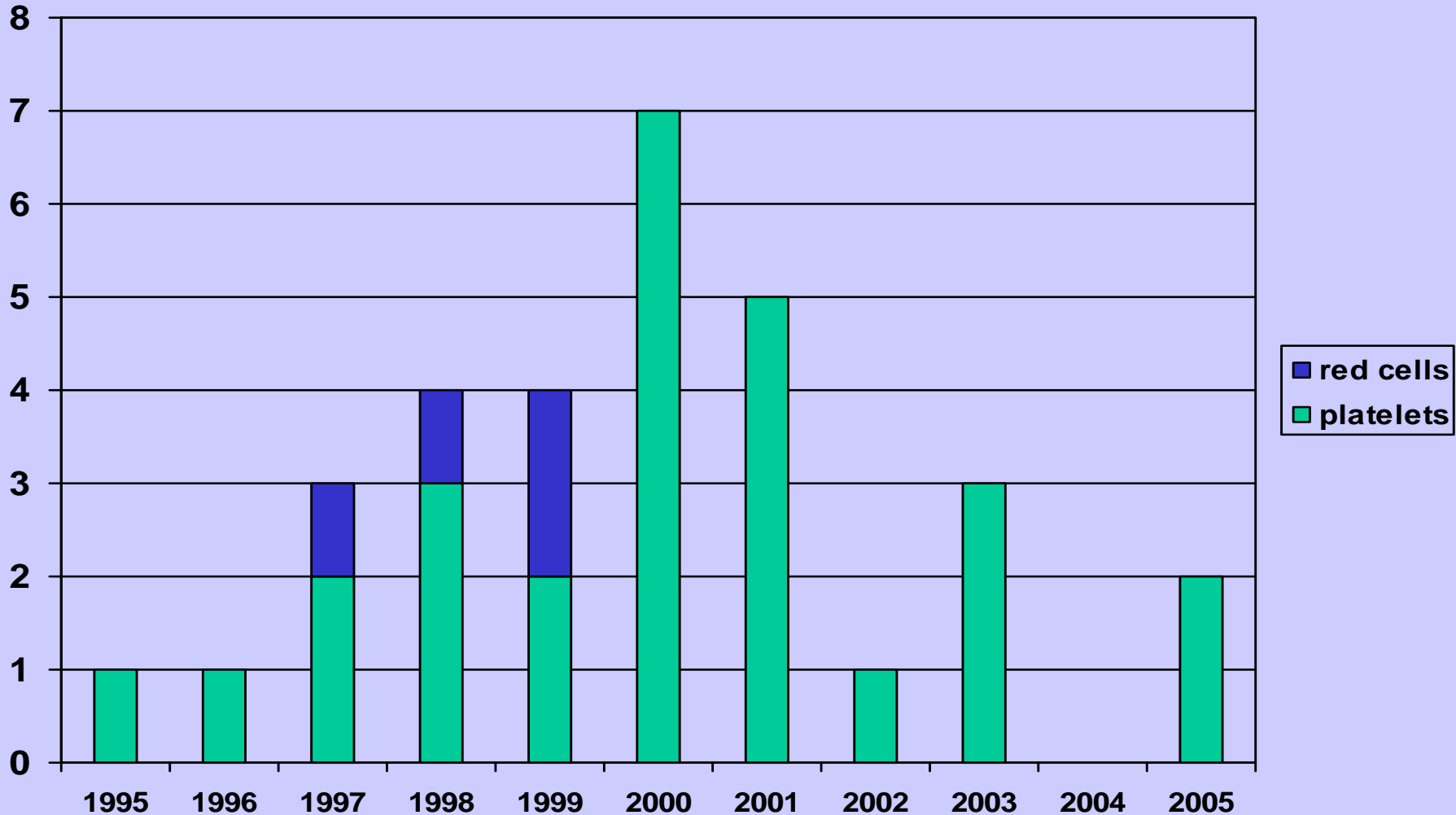
or

- At least one component received by the infected recipient was shown to contain the agent of infection

Transfusion transmitted infections 2005

- **46** cases of suspected transfusion transmitted infections were referred (41 in England & Wales, 5 in Scotland)
- **3** reports (1 HBV and 2 bacteria) were determined to be TTIs according to the definition.
- **2** reports were of predicted HAV transmissions.
- **40** cases were concluded as not TTIs
 - **14** HBV
 - **6** HCV
 - **1** dual HBV and HCV
 - **1** HTLV
 - **4** HIV
 - **14** bacteria
- **1** case of HCV is pending complete investigation
- **1** further report from the HPA of a clinical diagnosis of vCJD in a blood transfusion recipient.

Confirmed bacterial infections, by year of transfusion and type of unit transfused (Scotland included from 10/98)



Recommendations (1)

- Hospitals should continue to report & investigate all possible incidents of post-transfusion infection appropriately & adequately

Action: Hospital Transfusion Teams

- Donors should be reminded to report any infections developing post donation to their local blood centre.
- UK Blood Service collection teams should ensure donor selection guidelines are adhered to at all times in order to prevent transmission of blood borne infections

Action: UK Blood Services

Recommendations (2)

- Efforts to prevent bacterial contamination of blood components should continue. These include;
 - Continuation of diversion of the first 20-30 mL of the donation (likely to contain any organisms entering the collection needle from the venepuncture site).
 - Careful attention to adequate cleansing of donors' arms.
 - Adherence to BCSH guidelines (1999) with regard to the visual inspection of blood components for any irregular appearance immediately prior to transfusion.

Action: UK Blood Services, hospital transfusion laboratories, staff undertaking pre-transfusion bedside checking

Recommendations (3)

- Hospitals should consult the blood service about the investigation of transfusion reactions suspected to be due to bacteria. Attention should be paid to the sampling & storage of implicated units or their residues and packs returned to the blood service for testing.

Action: Hospital Transfusion Teams

General Recommendations

General recommendations (1)

- **‘Right patient- Right blood’**: This joint initiative between the NPSA, SHOT and the NBTC aims to reduce the risk of ABO incompatible transfusions by improving the safety of blood administration. Hospitals must act on the Safer Practice Notice ‘Right patient right blood’ within the required timescale. A crucial element of this initiative, also required by the Blood Safety and Quality Regulations 2005, is competency-based training, which must be implemented for ALL staff involved in the transfusion process. It is essential that hospital CEOs recognise that this is a necessary and ongoing process and will add to the workload of the HTT.

Action: Hospital CEOs

General recommendations (2)

- **Appropriate use of blood components:** Considerable progress has been made in limiting unnecessary transfusion of red cells, but the use of FFP and platelets continues to rise. Acute transfusion reactions are more frequent following transfusion of plasma-rich components than red cells and this year in 8/24 (33%) of severe allergic or anaphylactic reactions to FFP , including one fatality and 2 cases of serious morbidity, there did not appear to be a clear clinical indication for FFP use.

Current national BCSH guidelines on the appropriate use of FFP and platelets should be incorporated into local protocols that are readily available in relevant clinical and laboratory areas, included in induction and update training and subject to clinical audit.

Action: Consultant haematologists with responsibility for transfusion together with the HTC and HTT.

General recommendations (3)

- **Better Laboratory Practice:** Hospital laboratory errors occurred in 37% of all IBCT reports. An initiative aimed at improving practice in hospital transfusion laboratories is under way, led by the IBMS. In the meantime, local quality improvements must be supported and resources provided to underpin the development of quality systems. It is essential that the quality and responsiveness of hospital transfusion laboratories is maintained as Pathology Services in England face major reorganisation following the Carter report, with the possible development of independent Pathology Trusts and diversification of providers of pathology services.

Action: Hospital CEOs

General recommendations (4)

- **Avoid blood transfusions out of core hours:** Available data indicate that blood administration and pre-transfusion testing outside of core hours are less safe and should be avoided unless clinically essential. Hospitals planning to move to '24/7' working must employ adequate numbers of appropriately skilled clinical and laboratory staff to ensure transfusion safety. It may be useful to audit the occurrence of patient safety incidents in hospitals during different time periods.

Action: Hospital CEOs, consultant haematologists with responsibility for transfusion together with HTC and HTT.

General recommendations (5)

- **Investigation of serious transfusion reactions:** All serious transfusion reactions must be fully investigated. An update of BCSH guidelines is in progress.

Action: Consultant haematologists with responsibility for transfusion should implement current best practice.

General recommendations (6)

- **Communication of complex transfusion requirements:**
Failure to communicate special transfusion requirements is an important contributory factor in many cases of IBCT. Effective mechanisms must be developed for communication of information on complex transfusion requirements (eg for patients requiring irradiated components, those with allo-antibodies, stem-cell transplant recipients). The involvement of pharmacists in ‘flagging’ prescription of purine analogues is helpful in ensuring provision of irradiated components . Patient awareness and empowerment should be encouraged. Organisations should work together to implement and where necessary develop appropriate tools (eg documentation for patients transferred between hospitals, patient held booklets, standard antibody cards with accompanying advice).

Action: UK National and Regional Blood Transfusion Committees to facilitate and co-ordinate, Hospital CEOs to implement.

General recommendations (7)

- **Increase safety of routine antenatal anti-D prophylaxis:**
Reports of errors relating to anti-D immunoglobulin (Ig) administration are increasing, and 2 cases were reported in 2005 in which misinterpretation of the antenatal antibody investigation resulted in severe haemolytic disease of the foetus. Implementation of routine antenatal anti-D prophylaxis must be supported by education of primary care clinicians and hospital laboratory staff. Current legislation surrounding the issue and prescription of anti-D Ig requires clarification and is a potential source of system error. National guidelines on antenatal testing must be incorporated into agreed local policies and subject to clinical audit.

Action: Royal Colleges of Midwives, General Practitioners, Obstetricians and Gynaecologists, Consultant haematologists, HTC's and HTT's.

General recommendations (8)

- **Further measures by the blood services to reduce TRALI and bacterial contamination:** Measures implemented thus far appear to have reduced the risks of TRALI and bacterial contamination of platelets. Further measures require evaluation including the implications for availability and efficacy of blood components as well as cost-effectiveness.

Action: UK Blood Services, Department of Health (DH) advisory mechanisms.

Recommendations for future developments

(1)

- **Blood transfusion outside the hospital setting:** Against the background of a trend towards provision of care closer to the patient, there is a need for a standard of practice to be developed for transfusion in the community setting, including provision for appropriate management and reporting of adverse events.

Action: UK National Blood Transfusion Committees to facilitate and co-ordinate.

Recommendations for future developments

(2)

- **Need for clinical studies:** There is a paucity of good quality randomised studies from which to develop evidence-based transfusion practice. Well designed clinical studies should be undertaken to answer some of the questions that arise in clinical practice, including the optimal methods of patient identification, systems organisation and appropriate blood product support in different clinical settings. This will require action from clinical researchers, statistical and analytical support and assistance from funding bodies.

Action: UK National Blood Transfusion Committees, UK Blood Services, Funding bodies eg Health Technology Assessment and National Institute for Healthcare Research.

Recommendations for future developments

(3)

- **Future development of haemovigilance:** The implementation of the Blood Safety and Quality Regulations provides a unique opportunity to develop and re-enforce haemovigilance in the UK. It is essential that a structure is established that enables UK haemovigilance to flourish and to maintain its international recognition.

Action: DH, UK Blood Services, UK National Blood Transfusion Committees.